



Serial No. 10/790,562

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

*Hateboer et al.*

**Serial No.:** 10/790,562

**Filed:** March 1, 2004

**For:** RECOMBINANT PROTEIN  
PRODUCTION IN A HUMAN CELL

**Confirmation No.:** 9903

**Examiner:** W. Schlapkhol, Ph.D.

**Group Art Unit:** 1636

**Attorney Docket No.:** 2578-4038.3US

**NOTICE OF EXPRESS MAILING**

Express Mail Mailing Label Number \_\_\_\_\_

Date of Deposit with USPS: \_\_\_\_\_

Person making Deposit \_\_\_\_\_

**BUDAPEST TREATY DECLARATION**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Ronald Brus, hereby certify that I am the Chief Executive Officer of Crucell Holland BV ("Crucell") and declare that:

1. I am informed and believe that Crucell is the assignee of U.S. patent application 10/790,562 entitled RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL.

2. As evidenced by the attached Deposit Receipt, I am informed and believe that Crucell's predecessor in interest made a deposit of the PER.C6™ cell line, under ECACC deposit number 96022940 under the provisions of the Budapest Treaty with the Centre for Applied Microbiology and Research Authority (European Collection of Animal Cell Cultures), Porton Down, Salisbury, Wiltshire SP4, OJG, United Kingdom, an International Depository Authority, on February 29, 1996.

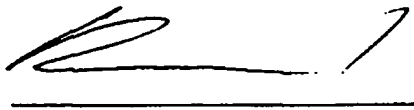
3. On behalf of Crucell, I state that all restrictions upon public access to the deposit (except those restrictions permitted by 37 C.F.R. § 1.808(b)) will be irrevocably removed upon the grant of a U.S. patent on this U.S. patent application, and the deposit will be replaced if viable samples cannot be dispensed by the depository.

4. I am informed and believe that the deposit was accepted by the International Depository Authority, effective at least as early as February 29, 1996.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of the patent.

6. Attached is a copy of the deposit receipt for ECACC deposit number 96022940.

Date: May 16, 2006

  
\_\_\_\_\_  
Ronald Brus



**Centre for Applied Microbiology and Research  
&  
European Collection of Cell Cultures**

This document certifies that Cell Culture  
(Deposit Ref. 96022940) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 29<sup>TH</sup> February 1996

..... P. J. Packer  
Dr P J Packer  
Quality Manager, ECACC



**CAMR**  
Centre for Applied Microbiology and Research

European Collection of Cell Cultures, CAMR, Salisbury, Wiltshire SP4 0JG UK

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TG

INTERNATIONAL FORM

CRUCELL HOLLAND B.V.  
ARCHIMEDESWEIG 4  
PO BOX 2048  
2301 CA LEIDEN  
THE NETHERLANDS

NAME AND ADDRESS  
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: PER C6	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 96022940
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by:	
<input checked="" type="checkbox"/> A scientific description	
<input type="checkbox"/> A proposed taxonomic designation	
(Mark with a cross where applicable)	
III. RECEIPT AND ACCEPTANCE	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 29 <sup>th</sup> February 1996 (date of the original deposit) <sup>1</sup>	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
IV. INTERNATIONAL DEPOSITORY AUTHORITY	
Name: Dr P J Packer	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):
Address: ECACC CAMR Porton Down Salisbury SP4 0JG	Date: 26/2/01 PJP/ckd

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository  
authority was acquired

## APPENDIX 3

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

CRUCELL HOLLAND B.V.  
ARCHIMEDESWEG 4  
PO BOX 2048  
2301 CA LEIDEN  
THE NETHERLANDS

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified on the following pageNAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: CRUCELL HOLLAND B.V.	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  96022940
Address: ARCHIMEDESWEG 4 PO BOX 2048 2301 CA LEIDEN THE NETHERLANDS	Date of the deposit or of the transfer: 29 <sup>th</sup> February 1996
III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on <sup>2</sup> . On that date, the said microorganism was	
<input checked="checked" type="checkbox"/> X	viable
<input type="checkbox"/>	no longer viable

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr P J Packer ECACC CAMR Address: Porton Down Salisbury Wiltshire SP4 0JG	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):  Date: 26/2/01 P. Shuck

4 Fill in if the information has been requested and if the results of the test were negative.